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amt agent selected from organic and inorganic acids and bases, a dosage form wherein the liquid, active agent formulation comprises a chelating agent.

IN THE CLAIMS:

Please amend the claims as follows.

1. (Amended) An active agent dosage form:
a first layer comprising an amount of swellable polymer sufficient to swell said first layer to a first length, said first length being sufficient to facilitate retention of said active agent dosage form within a stomach of a subject;
a second layer laminated with the first layer at a common surface, said second layer comprising a therapeutic amount of an active agent and being formulated to limit expansion of said second layer to a length less than said first length; and
at least one band of insoluble material circumscribing and binding together the first layer and the second layer.

a4 2. (Amended) The active agent dosage form of claim 1, wherein the number average molecular weight of the swellable polymer is between about 100,000 and 20,000,000 grams per mole.

3. (Amended) The active agent dosage form of claim 2, wherein the swellable polymer is polyethylene oxide, hydroxypropyl cellulose, hydroxypropyl methyl cellulose, hydroxyethyl cellulose, sodium carboxy methylcellulose, calcium carboxymethyl cellulose, methyl cellulose, polyacrylic acid, maltodextrin, pre-gelatinized starch, guar gum, sodium alginate, or polyvinyl alcohol.

4. (Amended) The active agent dosage form of claim 1, wherein the second layer comprises a hydroattractant selected from low-substituted hydroxypropyl cellulose,

microcrystalline cellulose, cross-linked sodium or calcium carboxymethyl cellulose, cellulose fiber, cross-linked polyvinyl pyrrolidone, cross-linked polyacrylic acid, a cross-linked ion exchange resin, alginates, colloidal magnesium-aluminum silicate, corn starch granules, rice starch granules, potato starch granules, sodium carboxymethyl starch, sugars, and sodium chloride, and the first layer optionally comprises a hydroattractant selected from low-substituted hydroxypropyl cellulose, microcrystalline cellulose, cross-linked sodium or calcium carboxymethyl cellulose, cellulose fiber, cross-linked polyvinyl pyrrolidone, cross-linked polyacrylic acid, cross-linked ion exchange resin, alginates, colloidal magnesium-aluminum silicate, corn starch granules, rice starch granules, potato starch granules, sodium carboxymethyl starch, sugars and sodium chloride.

Sub Box
5. (Amended) The active agent dosage form of claim 1, wherein the first layer swells more rapidly and to a greater extent than does the second layer.

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6. (Amended) The active agent dosage form of claim 5, wherein the active agent is an antiviral, antimicrobial, antidiabetic, antihyperglycemic, hypoglycemic, antidepressant, antiobesity or antifungal active agent.

7. (Amended) The active agent dosage form of claim 4, the second layer includes 5 to 99.99 weight percent of a swellable polymer and further includes up to 60 weight percent, inclusive, of the hydroattractant.

8. (Amended) The active agent dosage form of claim 1, wherein the first layer is formulated such that the active agent dosage form is retained within the stomach for a prolonged period of time.

Sub Box
9. (Amended) The active agent dosage form of claim 8, wherein the prolonged period of time is between about 6 to 12 hours.

10. (Amended) The active agent dosage form of claim 1, wherein the first layer

comprises polyethylene oxide having a number average molecular weight of at least 100,000 grams per mole.

11. (Amended) The active agent dosage form of claim 10, wherein the active agent is an antiviral, antimicrobial, antidiabetic, antihyperglycemic, hypoglycemic, antidepressant, antiobesity or antifungal active agent.

12. (Amended) The active agent dosage form of claim 11, wherein the active agent is acyclovir, ganciclovir, ritonavir, minocycline, cimetidine, ranitidine, captopril, methyldopa, selegiline, minocycline, fexofenadine, metformin, bupropion, orlistat or a pharmaceutically acceptable salt thereof.

13. (Amended) The active agent dosage form of claim 10, wherein the active agent is metformin or a pharmaceutically acceptable salt thereof.

14. (Amended) The active agent dosage form of claim 1, wherein the second layer comprises an active agent selected from the group consisting of acyclovir, ganciclovir, ritonavir, metformin, bupropion, orlistat and minocycline, and the second layer comprises a bioerodible polymer, wherein the dosage form is formulated to release a therapeutically-effective amount of the active agent to the stomach of a subject over at least a 3 hour period.

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15. (Amended) A method for treating a subject in need thereof with an active agent, the method comprising:
administering to the subject a multilayered dosage form which is retained in a stomach of the subject over a prolonged period of time, the dosage form comprising a first layer comprising an amount of swellable polymer sufficient to swell said first layer to a first length, said first length being sufficient to facilitate retention of said active agent dosage form within the stomach of a subject, and a second layer laminated with the first layer at a common surface, said second layer comprising a therapeutic amount of an active agent and being formulated to limit expansion of said second layer to a length less than said first length.

16. (Amended) The method of claim 15, which comprises administering one or more of the multilayered dosage forms to the subject in the fed state at the start of each dosing period.

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17. (Amended) The method of claim 16, wherein the administration of one or more of the multilayered dosage forms occurs within one hour of the subject consuming food.

18. (Amended) The active agent dosage form of claim 1, further comprising a gastric-emptying delaying agent.

19. (Amended) The active agent dosage form of claim 18, wherein the gastric-emptying delaying agent is selected from anticholinergic agents, methylcellulose, guar gum, fats and fatty acids of 10-15 carbon atoms.

20. (Amended) The active agent dosage form of claim 1, wherein the active agent comprises a liquid active agent formulation.

21. (Amended) The active agent dosage form of claim 20, wherein the liquid active agent formulation is sorbed into porous particles.

22. (Amended) The active agent dosage form of claim 21, wherein the porous particles are calcium hydrogen phosphate or magnesium aluminometasilicate.

23. (Amended) The active agent dosage form of claim 1, wherein the dosage form comprises a pH regulating agent.

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cont 24. (Amended) The active agent dosage form of claim 21, wherein the liquid active agent formulation comprises a pH regulating agent selected from organic and inorganic acids and bases.

25. (Amended) The active agent dosage form of claim 21, wherein the liquid active agent formulation comprises a chelating agent.

Please add the following new claim:

a⁵ 26. The active agent dosage form of claim 8, wherein the prolonged period of time is at least 3 hours.

REMARKS

The Office Action mailed February 27, 2001, has been received and reviewed. Claims 1 through 25 are currently pending in the application. Claims 1 through 25 stand rejected. Further, the Office Action sets forth various objections to both the specification and claims of the application. However, Applicants respectfully request reconsideration of the application in light of the amendments and remarks set forth herein.

Objections

The specification is objected to due to the informalities noted on Page 2 of the Office Action. Specifically, the Office has requested the replacement of the term "anticholenergic" on page 25, line 23 of the specification with the term "anticholinergic." Applicants respectfully